REMARKS

Claims 1-17 are pending in the application.

Claims 1-12 have been canceled.

Claim 13 has been amended.

Applicant has now amended claim13 to use the language "consisting essentially of".

The present invention as currently claimed provides a pharmaceutical formulation

A pharmaceutical formulation for oral administration having increased stability and bioavailability consisting essentially of a soft gelatin capsule which contains a therapeutically active amount of a Cox2 inhibitor dissolved in a composition consisting essentially of: 40% to 80% by weight glycofurol; 15% to 35% by weight of glycerin; 5% to 15% by weight water.

It should be noted that in the present invention there is no necessity to provide surfactants and a triglyceride as required by Chen et al. U.S. Patent No. 6,383,471.

CLAIM REJECTIONS UNDER 35 U.S.C. § 112

The rejection of claim 10 under 35 U.S.C. § 112, second paragraph has been rendered moot by virtue of cancellation of said claim.

DOUBLE PATENTING

The double patenting rejection of claim 1-12 under 35 U.S.C. § 101 has also been rendered moot as those claims have also been canceled.

CLAIM REJECTIONS UNDER 35 U.S.C. § 103

The rejection of claims 1-13 under 35 U.S.C. § 103(a) as being unpatentable over Chen, et al. U.S. patent No. 6,383,471 is respectfully traversed. Since claims 1-12 have been canceled, Applicant will address only the rejection as it applies to claim 13. Initially, it should be immediately noted that the composition of claim 13, does not require ionizing agents and accordingly are distinguishable from the Chen, et al reference.

The Examiner states that the *Chen et al.* U.S. Patent No. 6,383,471B1 teaches compositions for the improved delivery of hydrophobic therapeutic agents such as celecoxib, ibuprofen and naproxen. The compositions contains ionizing agents, solubilizers such as glycofurol, glycerol and water. Once again, no ionizing agents are present in Applicant's formulation of claim 13.

It is respectfully submitted that the disclosure of *Chen et al.* should be evaluated for what it fairly teaches. The invention of *Chen et al.* requires the positive presence of a carrier comprising:

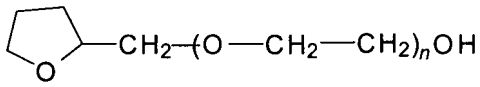
(i) an ionizing agent (***not present in Applicant's formulation of claim 13***) capable of ionizing the at least one ionizable functional group, wherein the ionizing agent is present in an amount of at least about 0.1 mole equivalents per mole of the at least one functional group;

(ii) a surfactant selected from the group consisting of non-ionic hydrophilic surfactants having an HLB value greater than or equal to about 10, ionic hydrophilic surfactants, hydrophobic surfactants having an HLB value less than 10, and mixtures thereof; and

(iii) a triglyceride.

Solubilizers such as glycofurol and glycerol may be added to the carrier system in addition to the important components of the *Chen et al.* invention which requires a surfactant having specific HLB values and a triglyceride.

In the present invention, no surfactants, or triglycerides are used in the solvent system of the invention. The solvent system of the invention is basically a mixture consisting essentially of 40% to 60% by weight of a polyoxyethylene ether of the formula:



wherein n = 1 to 6; 15% to 35% by weight of glycerin and 15% to 35% by weight water.

The solvent system of applicants' invention does not require the presence of the surfactants or triglycerides of *Chen et al.* The Examiners' attention is called to column 31, lines 28-39 wherein *Chen et al.* states that:

"The surfactant or surfactant mixture is present in an amount sufficient to promote the continued solubilization of the therapeutic agent in the gastrointestinal tract. Although small amounts of surfactant may provide some stabilization of the solubilized therapeutic agent, it is presently preferred to include a surfactant in an amount of at least about 10%, preferably about 20-90% by weight, based on the total weight of the composition. Also preferred are mixtures of surfactants, wherein the total amount of surfactant is at least

about 10%, and preferably about 20-90% by weight, based on the total weight of the composition."

Applicants' invention is devoid of surfactants and triglycerides.

Furthermore, Applicants' have reviewed the specific Examples where Glycofurol is used as the solvent in the *Chen et al.* '471 patent. The specific Examples where glycofurol is used as part of the solvent system in *Chen et al.* are Formulation Nos. 21, 30, 31, 36, and 58. The above Examples require the presence of a surfactant or mixtures of surfactants. ***It is further noted that none of the Examples of Chen et al. containing glycofurol incorporate glycerin which is required in the solvent system of Applicants' invention.***

The rejection of claims 14-17 under 35 U.S.C. § 103 (a) as being unpatentable over *Chen et al.* U.S. Patent No. 6,383,471B1 in view of Haskell U.S. Published Application No. 2002/0119200A1 is also courteously traversed. The Examiner states that Haskell lists the cyclooxygenase-2 inhibitors namely valdecoxib, rofecoxib, celecoxib and parecoxib. Applicants' respectfully submit that there is no motivation in *Chen et al.* in combination with Haskell to use the solvent system of the present invention which once again does not use ionizing agents. Accordingly the prior art is totally silent the instant formulation of the invention.

It is respectfully submitted that Chen et al. in view of Haskell does not render obvious the invention as recited in the amended claims.

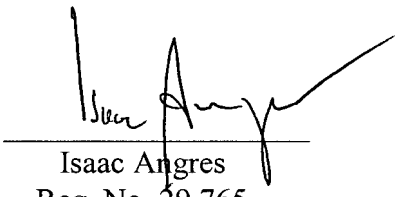
It is courteously submitted that the Office has failed to establish the criteria necessary to establish a *prima facie* case of obviousness as set forth in MPEP § 2142: the

cited reference must teach or suggest all the claim limitations; there must be some motivation or suggestion, either in the reference or in the knowledge available to the skilled artisan, to modify the reference to arrive at the claimed invention, and there must be a reasonable expectation of success. The cited primary reference of *Chen et al.* does not suggest the solvent system of the present invention.

CONCLUSION

For the above reasons, withdrawal of the rejections under 35 U.S.C. § 103 is believed to be proper in view of the amendments presented herein. An indication of a Notice of allowance is earnestly sought. The Examiner is kindly requested to contact the agent and/or attorney of record at the below-listed telephone number if there remain any issues that can be resolved telephonically.

Respectfully submitted,



Isaac Angres
Reg. No. 29,765

Date: September 4, 2007
2001 Jefferson Davis Highway - Suite 301
Arlington, VA 22202
(703) 418-2777
Procaps C1002A